

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION

This Document Relates To:
All Cases

MDL No. 2419

Master Dkt. No. 1:13-md-2419-RWZ

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**DEFENDANT UNIFIRST CORPORATION'S
MEMORANDUM IN SUPPORT OF ITS GLOBAL MOTION TO DISMISS**

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INTRODUCTION

Until December 2013, UniFirst had not been named a defendant in any of the more than 300 cases currently pending in this MDL. The reason for UniFirst's delayed entry into this case is clear: UniFirst has no liability here and was only named a defendant because the entity responsible for plaintiffs' tragic injuries, New England Compounding Pharmacy, Inc. ("NECC"), filed for bankruptcy. As conceded by plaintiffs in the Master Complaint ("Compl."), NECC engaged in "significant violations of pharmacy law and regulations that clearly placed the public's health and safety at risk." Compl. ¶ 75. Given NECC's bankruptcy filing, however, plaintiffs now attempt to shift the blame to numerous third parties, including UniFirst. *See* Compl. ¶ 3. Plaintiffs allege that UniFirst can be held liable for NECC's wrongdoing because UniFirst "failed to provide adequate cleaning services [to NECC] that would have prevented contamination of the drugs made in [NECC's] cleanrooms." Compl. ¶ 5. But there are at least two fundamental flaws in plaintiffs' theory that require dismissal of all claims against UniFirst.

First, the governing agreement between UniFirst and NECC makes clear that UniFirst never assumed any duty to prevent contamination in NECC's cleanrooms, and it certainly never assumed any duty to prevent contamination of NECC's products. Instead, UniFirst merely agreed that, **once per month**, in return for only \$865, two UniFirst employees would spend approximately 90 minutes at NECC performing certain ancillary cleaning services. These once-monthly cleanings in no way subsumed NECC's obligations under state law to maintain the sterility of its cleanrooms day-in and day-out in accordance with the standards established by "USP 797." *See* Compl. ¶ 46; Declaration of Abigail Hemani in Support of Defendant UniFirst Corporation's Global Motion to Dismiss ("Hemani Decl.") Ex. A (USP 797). Because the Master Complaint expressly alleges that NECC disregarded its legal obligations, and because the Master Complaint does not (and could not) allege that UniFirst reasonably could have foreseen

NECC's reckless, unlawful, and likely criminal malfeasance, UniFirst cannot be held liable to plaintiffs for negligence. *See infra* Argument § I.A.

Second, the allegations in the Master Complaint do not (and could not) give rise to a plausible inference that UniFirst played any role in causing plaintiffs' injuries. No matter how well UniFirst cleaned NECC's cleanrooms during its once-monthly visits, there is nothing that UniFirst could have done to prevent the harm that the Master Complaint expressly alleges was caused by NECC during the 99.8% of each month when UniFirst was not present. According to the Master Complaint, NECC: (1) failed to maintain a sealed cleanroom, such that contaminants moved into and out of the cleanroom freely at all times, *see* Compl. ¶ 83; (2) failed to follow legal requirements for cleanroom sterilization protocols, *see* Compl. ¶¶ 84-85; (3) disregarded a leaking boiler and proper standards for cleanroom ventilation, *see* Compl. ¶ 86; (4) failed to properly sterilize NECC's products, *see* Compl. ¶ 79; and (5) ignored test results clearly demonstrating that NECC's cleanrooms had been contaminated, *see* Compl. ¶ 94. Based on these allegations, it is clear that there was nothing UniFirst could do: even if UniFirst had performed its limited cleaning obligations perfectly, plaintiffs still would have suffered precisely the same injuries. Plaintiffs, therefore, have not adequately alleged causation. *See infra* Argument § I.B.

In short, it was NECC's responsibility to ensure that its products remained free of contaminants. Because UniFirst, by contrast, had no duty to ensure the sterility of either NECC's cleanrooms or its products, and because the allegations in the Master Complaint confirm that there was nothing UniFirst could have done to prevent NECC from causing plaintiffs' injuries, plaintiffs have failed to state a claim against UniFirst for negligence.

Each of the ancillary claims brought by plaintiffs against UniFirst also fails as a matter of law: Plaintiffs' M.G.L. Chapter 93A claim fails because (1) choice of law principles preclude plaintiffs—none of whom resides in Massachusetts or was injured here—from bringing suit under Chapter 93A; (2) the Master Complaint fails to give rise to any plausible inference that UniFirst's conduct caused plaintiffs' alleged injuries; and (3) the Master Complaint fails to allege that UniFirst engaged in any "unfair" or "deceptive" conduct. Plaintiffs' claims against UniFirst for wrongful death, loss of consortium, and punitive damages fail, as those claims cannot be sustained absent a viable primary claim. Plaintiffs also have not alleged that UniFirst acted with the willful, wanton, or malicious intent necessary for a punitive damages award.

For all of these reasons, plaintiffs' claims against UniFirst should be dismissed in their entirety and with prejudice.

FACTUAL BACKGROUND

A. The Allegations in the Master Complaint

1. The Master Complaint Alleges that NECC Caused Plaintiffs' Injuries.

According to the Master Complaint, Barry Cadden and the Conigliaro family founded NECC in 1998. Compl. ¶¶ 29-34. NECC ostensibly was a compounding pharmacy—*i.e.*, a pharmacy that prepares unique formulas for medications that are not available commercially, such as compounds for patients who are allergic to an ingredient in a mass-produced product. Compl. ¶ 43. The NECC compounding facility was located in Framingham, Massachusetts, in the same building that housed the Conigliaro family's recycling plant, which recycled everything from plastic to metal to mattresses. Compl. ¶¶ 26, 29.

In September 2012, the Tennessee Department of Health notified the Center for Disease Control and the Massachusetts Department of Public Health ("MDPH") of a series of fungal meningitis cases following injections of methylprednisolone acetate ("MPA") compounded at

NECC. Compl. ¶¶ 60-62. Upon conducting thorough investigations of NECC, the MDPH and the federal Food and Drug Administration (“FDA”) found “serious deficiencies and significant violations of pharmacy law and regulations that clearly placed the public’s health and safety at risk.” Compl. ¶ 75 (quoting MDPH Preliminary Investigation Findings, at 2, attached as Compl. Ex. A). As alleged in the Master Complaint, the MDPH found, among other things:

- “The clean rooms used [by NECC] to compound the drugs were not appropriately sealed, allowing contaminants to infiltrate the room, and exposing the drugs to contamination.” Compl. ¶ 83.
- “Powder hoods [used] during medication preparation . . . were not thoroughly cleaned pursuant to USP 797 or pursuant to NECC standard operating procedures,” as residual powder was found within the hoods. Compl. ¶ 84.
- “‘Tacky mats’ used to trap dirt, dust, and other potential contaminants from shoes prior to clean room entry were visibly soiled with debris, in violation of USP 797.” Compl. ¶ 85.
- “A leaky boiler next to the clean room created an environment susceptible to contaminant growth, including a pool of standing water.” Compl. ¶ 86.
- NECC did not follow the procedure set forth in USP 797 or its own standard operating procedures for sterilizing its product in the autoclave machine. Compl. ¶ 79.¹
- NECC delivered several shipments of MPA before receiving final sterility testing results. Compl. ¶ 79.
- NECC “distributed large batches of [products] to facilities apparently for general use[,] rather than requiring a prescription for an individual patient, in violation of its state pharmacy license” and Massachusetts law. Compl. ¶ 80.

The FDA also uncovered significant irregularities at NECC, many of which violated federal law. Compl. ¶ 88. As alleged in the Master Complaint:

- Despite the fact that NECC’s formula worksheets stated that the raw materials used to create its products were sterile, the FDA determined that NECC used non-sterile raw

¹ An autoclave is a device used to sterilize equipment and supplies by subjecting them to high pressure saturated steam. See The Commonwealth of Massachusetts Executive Office Of Health And Human Services, New England Compounding Center (NECC): *Preliminary Investigation Findings*, October 23, 2012 (“MDPH Preliminary Investigation Findings”), at 2, attached as Compl. Ex. A.

materials in its preservative-free MPA and other injectable products. Compl. ¶ 92. And, although NECC claimed that it used its autoclave system to sterilize this non-sterile material, the FDA noted that NECC provided no documentation that this sterilization procedure worked. Compl. ¶ 93. The FDA also observed tarnish, condensation and discoloration in the autoclaves and puddles of water in the base of the autoclave chamber. Compl. ¶ 93.

- Between January and September 2012, on at least 38 occasions, NECC’s internal environmental monitoring program recorded levels of bacteria in NECC’s cleanrooms above the level where NECC was supposed to “take action” under USP 797, and 18 instances where the level of mold exceeded this “action limit.” Compl. ¶ 94.² But NECC took no action to investigate or correct this contamination, as required by USP 797. Compl. ¶ 94.
- The plastic and mattress recycling facility next door to NECC’s cleanrooms produced dust and other airborne contaminants, and NECC’s HVAC units were located only 100 feet from the recycling facility. Compl. ¶ 96.
- NECC turned off the air conditioning overnight, which encouraged microbial growth. Compl. ¶ 97.
- A boiler near NECC’s cleanroom was leaking water and creating puddles that contained a thick white debris and thick black granular material. Compl. ¶ 98.

Following the issuance of the MDPH and FDA reports, several state and federal authorities, including the Department of Justice, the Commonwealth of Massachusetts, and other state Attorneys General, announced that they were conducting criminal investigations of NECC and its affiliates. Compl. ¶ 119.

2. **The Master Complaint Makes Only Limited Allegations Against UniFirst.**

Against this backdrop of widespread unlawful (and likely criminal) malfeasance by NECC, the Master Complaint asserts only a handful of benign allegations against UniFirst. According to the Master Complaint, UniFirst “was hired by NECC to clean the . . . clean rooms

² Compounding pharmacies are required to perform regular testing for microbes in the air and on surfaces of the cleanroom. Hemani Decl. Ex. A (USP 797), at 14, 35. When the level of microbes rises above a designated “action level,” the pharmacy is required to conduct “[a]n investigation into the source of the contamination,” and then to eliminate that source, clean the affected area, and perform resampling. *Id.* Results above the “action level” also “should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location.” *Id.*

where the contaminated products were manufactured.” Compl. ¶ 5. More specifically, plaintiffs allege that UniFirst entered into a Contamination Control Service Agreement (“CCSA”) with NECC, pursuant to which UniFirst was required, “each month,” to perform certain “duties [] outlined in a Service Schedule attached and incorporated into the CCSA.” Compl. ¶¶ 141-44.

The CCSA relied on in the Master Complaint makes clear that UniFirst’s cleaning obligations at NECC were, in fact, extremely limited.³ According to the CCSA, UniFirst employees serviced only NECC’s Framingham facility, on only one occasion per month, and, during that visit, they were responsible for providing only limited cleaning services in NECC’s “2 Class 10,000 Cleanroom and Anterooms,” including (1) emptying and washing all trash receptacles, and (2) cleaning and sanitizing the cleanroom floors, walls, and ceilings, the exteriors of the powder hoods, and the cleanroom “pass through.” Hemani Decl. Ex. B (CCSA), at 3. Notably, UniFirst was not permitted (much less obligated) to clean the interior of the hoods, where NECC actually engaged in its compounding activity. Nor was UniFirst authorized to clean the autoclave machines, where NECC allegedly sterilized its products. *See id.* In exchange for these monthly services, NECC paid UniFirst \$865 per month. *Id.* at 4.

Ignoring the limited scope of the CCSA, plaintiffs allege in the Master Complaint that “UniFirst failed to provide adequate cleaning services that would have prevented contamination of the drugs made in [NECC’s] cleanrooms.” Compl. ¶ 5. According to the Master Complaint, because “[a]spERGILLUS niger [*i.e.*, fungus] was found or brought into the NECC facility[,] UniFirst [necessarily] failed to perform the job it was hired to do.” Compl. ¶ 148.

³ Although courts generally do not consider materials outside the complaint when reviewing a motion to dismiss under Rule 12(b)(6), they may consider “documents central to plaintiffs’ claim” or “documents sufficiently referred to in the complaint.” *Gargano v. Liberty Int’l Underwriters, Inc.*, 572 F.3d 45, 47 n.1 (1st Cir. 2009). Because the CCSA is expressly referenced in the Master Complaint and forms the basis of the duty that plaintiffs allege UniFirst breached, the CCSA is precisely the kind of document that may be considered on a motion to dismiss.

Plaintiffs also make certain limited allegations about the conduct of UniFirst's employees in carrying out their monthly duties. In particular, plaintiffs allege that UniFirst employees "entered the NECC facilities (including the anterooms) in street clothes," brought into NECC's facility cleaning equipment that had not been sufficiently sanitized, and failed to wipe their footwear on the "floor mats" used in the room entry process. Compl. ¶ 145.⁴ According to plaintiffs, "[a]s a result of these failures . . . UniFirst (solely or in concert with NECC) negligently allowed contaminants . . . into every cleanroom where recalled products were made, composed, mixed, prepared, packaged and stored." Compl. ¶ 149.

B. The Requirements of USP 797

Massachusetts law requires compounding pharmacies to follow the standards established by the U.S. Pharmacopeia, including the standards for sterile compounding set forth in USP 797. *See* 247 CMR § 9.01(3); Compl. ¶¶ 45, 54.⁵ Under USP 797, "compounding personnel are responsible for ensuring that [compounded drugs] are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed." Hemani Decl. Ex. A (USP 797), at 3 (emphasis added). Under USP 797—and, thus, under Massachusetts law—"compounding personnel" must clean and disinfect all compounding surfaces frequently, "including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual [products], when there are spills, and when surface contamination is known or suspected from procedural breaches." *Id.* at 15-16, Table 3. USP 797 also specifies that other counters, work surfaces and floors in the vicinity of the compounding surfaces must be cleaned and disinfected at least daily. *Id.* at 15. Only the

⁴ Ironically, these "floor mats" that plaintiffs claim UniFirst employees should have used to wipe their feet are the very same mats that plaintiffs elsewhere allege were "filthy" and "visibly soiled with debris." Compl. ¶¶ 85, 99.

⁵ Indeed, the Master Complaint repeatedly relies on NECC's failure to adhere to the standards in USP 797 as evidence of NECC's gross misconduct. Compl. ¶¶ 79, 84, 85.

cleanroom walls, ceilings, and shelving can be cleaned on a monthly basis. *Id.* at 16. And it was only such a limited “monthly” cleaning that UniFirst was engaged to perform at NECC.

ARGUMENT

To survive a motion to dismiss, a complaint must plead facts that “state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *Rederford v. U.S. Airways, Inc.*, 589 F.3d 30, 35 (1st Cir. 2009) (same). “Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.” *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). Factual allegations that are merely “consistent with” unlawful conduct are insufficient to state a plausible claim where “more likely explanations” or “obvious alternative explanation[s]” exist. *Id.* at 681-82.

Here, the allegations in the Master Complaint make clear the fundamental and incurable flaw in plaintiffs’ case against UniFirst: Plaintiffs have not alleged (and could not allege) that UniFirst is responsible for their injuries. To the contrary, the alleged facts—based on findings of the FDA and MDPH investigations—support a far “more likely explanation[,]” *id.*, for plaintiffs’ harm: the malfeasance of NECC. The Master Complaint pleads that it was NECC that recklessly and unlawfully allowed contaminants to infiltrate its cleanrooms; it was NECC that recklessly and unlawfully allowed those contaminants into its products; and it was NECC that recklessly and unlawfully distributed those contaminated products to plaintiffs. Because UniFirst employees spent only 90-minutes per month at NECC, and because UniFirst is not alleged to have had any awareness of, or control over, NECC’s failure to maintain the sterility of its cleanrooms and its products during the remaining 99.8% of each month, the Master Complaint does not, and could not, state a plausible claim for relief against UniFirst.

I. PLAINTIFFS' NEGLIGENCE CLAIM AGAINST UNIFIRST (COUNT II) FAILS AS A MATTER OF LAW.

Plaintiffs' negligence claim against UniFirst fails because plaintiffs have not pleaded (and could not plead) that UniFirst either (1) violated any duty owed to plaintiffs, or (2) caused the injuries about which plaintiffs complain.⁶

A. Plaintiffs' Negligence Claim Against UniFirst Fails Because the Facts Alleged in the Master Complaint Establish that UniFirst Did Not Owe the Plaintiffs Any Duty.

Under the common law of every potentially relevant jurisdiction,⁷ to state a claim for negligence, a plaintiff must allege facts establishing that the defendant owed him a duty of care. In this case, by contracting with NECC to perform only a limited subset of NECC's cleaning and sterilization requirements, UniFirst did not acquire a duty of care that extended to the hundreds of thousands of consumers of NECC products across the nation.

Duty is a question of law, to be determined by the Court.⁸ Where a defendant engages in an undertaking, that defendant acquires a duty to perform that undertaking with care, but such duty extends only to those individuals whose injury is a reasonably foreseeable consequence of

⁶ Although the issues raised in this motion concerning reasonable foreseeability are sometimes deemed questions of "duty" and sometimes deemed questions of proximate causation, that is a distinction without a difference where, as here, the facts alleged fail to give rise to any plausible inference that plaintiffs' injuries were a reasonably foreseeable consequence of defendant's allegedly negligent conduct. *See, e.g.,* W. Jonathan Cardi, *The Hidden Legacy of Palsgraf: Modern Duty Law in Microcosm*, 91 B.U. L. Rev. 1873 (Dec. 2011).

⁷ Potentially relevant jurisdictions include the states in which plaintiffs reside or were injured, including Alabama, Florida, Illinois, Indiana, Kentucky, Maryland, Michigan, Minnesota, New Hampshire, New Jersey, North Carolina, Ohio, Rhode Island, South Carolina, Tennessee, Texas, and Virginia. UniFirst also would be entitled to dismissal under Massachusetts law although UniFirst does not believe that Massachusetts law governs any of plaintiffs' claims, given that no plaintiff resides or was injured in the Commonwealth. *See infra* Section II.A.

⁸ *See, e.g., Webb v. Jarvis*, 575 N.E.2d 992, 995 (Ind. 1991) ("Whether the law recognizes any obligation on the part of a particular defendant to conform his conduct to a certain standard for the benefit of the plaintiff is a question of law."); *Hill v. Sears, Roebuck & Co.*, 822 N.W.2d 190, 195 (Mich. 2012) ("Whether a defendant owes a plaintiff a duty of care is a question of law decided by the circuit court."); *Estate of Desir ex rel. Estiverne v. Vertus*, 69 A.3d 1247, 1258 (N.J. 2013) ("It has long been true that determinations of the scope of duty in negligence cases has traditionally been a function of the judiciary.") (internal quotations omitted); *Giggers v. Memphis Hous. Auth.*, 277 S.W.3d 359, 365 (Tenn. 2009) ("Traditionally, the question of whether a defendant owes a duty of care to the plaintiff is a question of law to be determined by the courts."); *A.H. v. Rockingham Pub. Co., Inc.*, 495 S.E.2d 482, 485 (Va. 1998) ("Whether such duty exists is 'a pure question of law.'").

any breach of the duty. As the Supreme Court of Indiana has explained, the “imposition of a duty is limited to those instances where a reasonably foreseeable victim is injured by a reasonably foreseeable harm.” *Webb v. Jarvis*, 575 N.E.2d 992, 997 (Ind. 1991).⁹

Here, plaintiffs ignore the limited scope of the duty undertaken by UniFirst in the CCSA—its contract with NECC. Plaintiffs complain that “UniFirst failed to provide adequate cleaning services that would have prevented contamination of the drugs made in [NECC’s] cleanrooms,” Compl. ¶ 5, but they do not (and could not) allege that UniFirst ever undertook to provide NECC with cleaning sufficient to “prevent[] contamination,” Compl. ¶ 5. Similarly, plaintiffs allege that UniFirst must have “failed to perform the job it was hired to do” because “[a]spergillus niger was found or brought into the NECC facility,” Compl. ¶ 148, without so much as acknowledging that UniFirst was not hired to prevent fungus from being transported into NECC’s cleanrooms—it was merely hired to provide limited, ancillary cleaning services, one morning per month.

The Master Complaint also alleges that, on the one morning per month that UniFirst employees came to NECC, they “allow[ed] contaminants” into NECC’s facility by “enter[ing] the NECC’s facilities . . . in street clothes,” by failing to adequately sanitize certain cleaning

⁹ See also *Hill v. Sears, Roebuck & Co.*, 822 N.W.2d 190, 196 (Mich. 2012) (“Before a duty can be imposed, there must be a relationship between the parties and the harm must have been foreseeable... If either of these two factors is lacking, then it is unnecessary to consider any of the remaining factors.”) (internal quotations omitted); *J.S. v. R.T.H.*, 714 A.2d 924, 928 (N.J. 1998) (“Foreseeability of the risk of harm is the foundational element in the determination of whether a duty exists.”); *Giggers v. Memphis Hous. Auth.*, 277 S.W.3d 359, 365-66 (Tenn. 2009) (“no duty will arise when a risk of injury is not generally foreseeable”) (internal quotations omitted); *Norfolk Shipbuilding & Drydock Co., Inc. v. Scovel*, 397 S.E.2d 884, 886 (Va. 1990) (holding that a duty exists “if an ordinarily careful and prudent person ought, under the same or similar circumstances, to have anticipated that an injury might probably result from the negligent acts”); see also *Pritchett v. ICN Med. Alliance, Inc.*, 938 So. 2d 933, 937 (Ala. 2006); *Malicki v. Doe*, 814 So. 2d 347, 362 (Fla. 2002); *City of Chicago v. Beretta U.S.A. Corp.*, 821 N.E.2d 1099, 1125 (Ill. 2004); *Dick’s Sporting Goods, Inc. v. Webb*, 413 S.W.3d 891, 897 (Ky. 2013); *100 Inv. Ltd. P’ship v. Columbia Town Ctr. Title Co.*, 60 A.3d 1, 11 (Md. 2013); *Domagala v. Rolland*, 805 N.W.2d 14, 26 (Minn. 2011); *Macie v. Helms*, 934 A.2d 562, 565 (N.H. 2007); *Stein v. Asheville City Bd. of Educ.*, 626 S.E.2d 263, 267 (N.C. 2006); *Wallace v. Ohio Dep’t of Commerce*, 773 N.E.2d 1018, 1026 (Ohio 2002); *Selwyn v. Ward*, 879 A.2d 882, 887 (R.I. 2005); *Charleston Dry Cleaners & Laundry, Inc. v. Zurich Am. Ins. Co.*, 586 S.E.2d 586, 588 (S.C. 2003); *City of Waco v. Kirwan*, 298 S.W.3d 618, 624 (Tex. 2009).

equipment, and by “fail[ing] to clean or wipe [their] shoes, boots and other footwear on floor mats used in the room entry process.” Compl. ¶¶ 145, 221. But, even if true, these allegations would be insufficient to give rise to any duty owed by UniFirst to the plaintiffs, as it would not have been reasonably foreseeable to UniFirst or its employees that such conduct could have resulted in any injury to consumers of NECC’s products, let alone the significant injuries alleged here. *See, e.g., Webb*, 575 N.E.2d at 995 (“Imposition of a duty is limited to those instances where a reasonably foreseeable victim is injured by a reasonably foreseeable harm.”). Instead, as the Master Complaint all but concedes, it was only because of NECC’s horrific malfeasance—unforeseeable to UniFirst—that contaminants made their way from the cleanroom, into NECC’s products, and to the plaintiffs.

As USP 797 recognizes, it is impossible to prevent bacteria and other contaminants from entering a cleanroom entirely.¹⁰ Indeed, it is precisely because some cleanroom contamination is inevitable that USP 797 imposes on compounding pharmacies numerous safeguards designed to prevent contaminants from making their way from the cleanroom into the compounded products. Although it was not reasonably foreseeable to UniFirst or its employees that NECC would ignore each of these safeguards—and ignore the law—that is precisely what the Master Complaint alleges that NECC did. For example:

- Under USP 797, NECC was required to take corrective action when levels of mold and bacteria in its cleanrooms rose above action levels. *See* Hemani Decl. Ex. A (USP 797), at 14-15. Plaintiffs allege that NECC ignored this requirement. *See* Compl. ¶¶ 94, 95, 111, 114.
- Under USP 797, NECC was required to decontaminate all surfaces where compounding took place at least daily, and at least every 30 minutes while compounding. *See supra* at 7. Plaintiffs allege that NECC ignored this requirement. Compl. ¶ 84.

¹⁰ *See* Hemani Decl. Ex. A (USP 797), at 4 (noting that the standards are designed to prevent “excessive bacterial endotoxin contamination” (emphasis added)).

- Under USP 797, NECC was required to keep products in the autoclave for at least 20 minutes in order to ensure sterilization. Plaintiffs allege that NECC ignored this requirement. Compl. ¶ 79.
- Plaintiffs allege that NECC sent out several shipments of MPA before receiving final results from sterility testing. Compl. ¶ 77.
- Plaintiffs allege that NECC “distributed large batches of [products] to facilities apparently for general use[,] rather than requiring a prescription for an individual patient, in violation of its state pharmacy license” and Massachusetts law. Compl. ¶¶ 80-81.
- Plaintiffs allege that NECC used non-sterile raw materials in its preservative-free MPA and other injectable products, despite representing otherwise on its formula worksheets. Compl. ¶ 92.
- Plaintiffs allege that NECC created a cleanroom environment that was particularly “susceptible to contaminant growth” by, among other things, failing to maintain air-conditioning in the cleanroom overnight. Compl. ¶¶ 86, 97.

In short, the Master Complaint alleges that NECC engaged in wholesale, systemic disregard for the numerous legally mandated safeguards designed to prevent pharmaceutical contamination. The Master Complaint does not (and could not) allege any facts suggesting either that UniFirst was aware of NECC’s malfeasance, or that it had any duty to prevent it. Instead, the only plausible inference from the Master Complaint is that UniFirst’s employees could not reasonably have foreseen that anything they did (or did not do) during their once-monthly visits to NECC could have resulted in the horrific injuries at issue in this case. Accordingly, plaintiffs have not alleged (and could not allege) that UniFirst owed them any duty, and their negligence claims against UniFirst must be dismissed.¹¹

¹¹ In addition to the arguments presented here, there are numerous reasons why, under the law of particular states that may be relevant to a subset of cases, plaintiffs’ allegations are insufficient to establish that UniFirst owed a duty to plaintiffs. In Indiana, for example, “contractors do not owe a duty of care to third parties after the owner has accepted the work.” *Jacques v. Allied Bldg. Servs. of Indiana, Inc.*, 717 N.E.2d 606, 608 (Ind. Ct. App. 1999). Because this and other arguments are not common to all plaintiffs, however, we reserve them for subsequent motions to dismiss the individual cases.

B. Plaintiffs' Negligence Claim Against UniFirst Fails Because the Facts Alleged in the Master Complaint Do Not Give Rise to Any Plausible Inference that UniFirst Caused Plaintiffs' Alleged Harm.

Under the law of all relevant jurisdictions, plaintiffs must plead not only that UniFirst owed them a duty, but also that UniFirst's alleged breach of that duty caused their harm. Indeed, plaintiffs must plead two distinct types of causation: "but for" causation and "proximate" causation. "But for" causation exists where, but for the conduct alleged, plaintiffs would not have suffered the claimed injury.¹² "Proximate cause puts a limit on the causal chain, such that, even [where] the plaintiff's injury would not have happened but for the defendants' breach, defendants will not be held liable for injuries that were not substantially caused by their conduct or were not reasonably foreseeable results of their conduct." *Hale v. Ostrow*, 166 S.W.3d 713, 719 (Tenn. 2005). Because the Master Complaint in this case does not (and could not) allege that UniFirst's conduct was either a "but for" or a proximate cause of plaintiffs' alleged injuries, the claims against UniFirst must be dismissed.¹³

¹² See *Skinner v. Square D Co.*, 516 N.W.2d 475, 479 (Mich. 1994) ("The cause in fact element generally requires showing that 'but for' the defendant's actions, the plaintiff's injury would not have occurred."); *Cowe by Cowe v. Forum Grp., Inc.*, 575 N.E.2d 630, 635 (Ind. 1991) ("An essential element in a cause of action for negligence is... at a minimum, causation in fact—that is, that the harm would not have occurred 'but for' the defendant's conduct.") (internal citations omitted); *Wood v. Newman, Hayes & Dixon Ins. Agency*, 905 S.W.2d 559, 562 (Tenn. 1995) ("To rephrase the issue in the classic language of causation in fact, would the plaintiff's loss have not occurred 'but for' the defendant's failure."); *Sugarland Run Homeowners Ass'n v. Halfmann*, 535 S.E.2d 469, 474 (Va. 2000) ("[G]enerally a person is not liable to another unless but for that person's negligent act the harm would not have occurred.") (internal quotation marks and citations omitted); *Vuocolo v. Diamond Shamrock Chems. Co.*, 573 A.2d 196, 199 (N.J. App. Div. 1990) ("It is fundamental that in order to visit tort liability upon a defendant a plaintiff must prove tortious conduct, injury and proximate cause... an act or omission is not regarded as a cause of an event if the event would have occurred without such act or omission.") (internal quotation marks and citations omitted); see also *Springer v. Jefferson Cnty.*, 595 So. 2d 1381, 1383 (Ala. 1992); *Tieder v. Little*, 502 So. 2d 923, 925 (Fla. Dist. Ct. App. 1987); *Thacker v. UNR Indus., Inc.*, 603 N.E.2d 449, 455 (Ill. 1992); *Trail-Likoy v. Saint Joseph Healthcare, Inc.*, 2006 WL 2193496 (Ky. Ct. App. Aug. 4, 2006); *Sindler v. Litman*, 887 A.2d 97, 110 (Md. App. 2005); *Schmitz v. Rinke, Noonan, Smoley, Deter, Colombo, Wiant, Von Korff & Hobbs, Ltd.*, 783 N.W.2d 733, 741 (Minn. Ct. App. 2010); *Carignan v. New Hampshire Int'l Speedway, Inc.*, 858 A.2d 536, 541 (N.H. 2004); *Barefoot v. Joyner*, 154 S.E.2d 543, 548 (N.C. 1967); *Anderson v. St. Francis-St. George Hosp., Inc.*, 671 N.E.2d 225, 227 (Ohio 1996); *Almonte v. Kurl*, 46 A.3d 1, 18 (R.I. 2012); *Hurd v. Williamsburg Cnty.*, 579 S.E.2d 136, 144 (S.C. Ct. App. 2003) *aff'd*, 611 S.E.2d 488 (S.C. 2005); *Sw. Key Program, Inc. v. Gil-Perez*, 81 S.W.3d 269, 274 (Tex. 2002).

¹³ Although causation typically is decided by the finder-of-fact, where, as here, the only plausible inference from the facts alleged is that causation is lacking, courts may grant a motion to dismiss. See, e.g., *Blackstone Realty LLC v. FDIC*, 244 F.3d 193 (1st Cir. 2001) (noting that, where the only plausible conclusion from the facts

1. Plaintiffs Have Not Alleged “But For” Causation.

According to the Master Complaint, even if UniFirst executed perfectly its limited obligations under the CCSA, plaintiffs still would have suffered precisely the same injuries. The Master Complaint concedes that contaminants were entering NECC’s cleanrooms continuously, day-in and day-out. Most notably, plaintiffs allege that “[t]he clean rooms used [by NECC] to compound the drugs were not appropriately sealed, allowing contaminants to infiltrate the room, and exposing the drugs to contamination.” Compl. ¶ 83.¹⁴ The only plausible inference, then, is that NECC’s products would have been “expos[ed] . . . to contamination”—and plaintiffs would have been injured—irrespective of anything that UniFirst’s employees did or could have done during the 90-minutes per month that they visited NECC. The Master Complaint therefore admits that UniFirst’s conduct is not a “but for” cause of plaintiffs’ harm.

That plaintiffs would have suffered the same injuries absent any alleged negligence by UniFirst is all the more apparent when one considers the allegations in the Master Complaint about NECC’s affiliate, Ameridose—another pharmaceutical company owned and run by Barry Cadden and the Conigliaro family.¹⁵ Upon inspecting Ameridose’s facility in Westborough,

pleaded in a complaint is that proximate causation is lacking, the court should dismiss the claim on the pleadings); *Hale v. Ostrow*, 166 S.W.3d 713, 718 (Tenn. 2005) (“Cause in fact and proximate cause are ordinarily jury questions, unless the uncontroverted facts and inferences to be drawn from them make it so clear that all reasonable persons must agree on the proper outcome.”) (internal quotation marks omitted); *Nichols v. Dobler*, 655 N.W.2d 787, 788 (Mich. Ct. App. 2002) (“Generally, proximate cause is a factual issue to be decided by the trier of fact. However, if reasonable minds could not differ regarding the proximate cause of the plaintiff’s injury, the court should decide the issue as a matter of law.”); *Fluehr v. City of Cape May*, 732 A.2d 1035, 1041 (N.J. 1999) (“Proximate cause as an issue, [] may be removed from the factfinder” where “reasonable minds could not differ on whether that issue has been established.”).

¹⁴ See also MDPH Preliminary Investigation Findings, at 8, attached as Compl. Ex. A (noting that “[g]aps were observed between sliding doors, located at the transition between the Prep Room (ISO 8) and the warehouse, despite being fully closed”). Moreover, both the Master Complaint and the CCSA reference a “pass through in the wall” of NECC’s cleanroom. Hemani Decl. Ex. B (CCSA), at 3; Compl. ¶ 100.

¹⁵ In 2006, Barry Cadden and the Conigliaros founded Ameridose, whose business was to prefill syringes and break down vats of liquid medications into smaller intravenous bags for individual treatments. Compl. ¶ 37. At all relevant times, Ameridose’s facilities were located in Westborough, MA. Compl. ¶ 39.

MA—where UniFirst did not clean¹⁶—the FDA found: (1) “[b]rownish structures,” “whitish, opaque structures,” rust, broken glass, “foreign material” and “thick residues” in and around the metal hoods used to prepare pharmaceutical products; (2) “[p]enetrating leaks” in the roof above the cleanroom (which Ameridose addressed by putting out totes to catch the streaming rain water); (3) walls in a room used to prepare purportedly sterile drug products that were cracked, corroded, and covered with a sticky materials; (4) a bird in the area where sterile finished product was packaged and stored; and (5) “insect infestations within 3-10 feet of the controlled area where sterile products were made.” Compl. ¶¶ 109, 116, 118. Not surprisingly, Ameridose’s products, like NECC’s products, were contaminated. *See* Compl. ¶¶ 109-118. The allegations in the Master Complaint thus suggest that NECC’s principals engaged in a pattern of reckless and unlawful behavior that would have resulted in product contamination irrespective of anything that UniFirst’s employees allegedly did wrong during their once-monthly visit to NECC.

2. **Plaintiffs Have Not Alleged Proximate Causation.**

Even if the Master Complaint adequately alleged “but for” causation, the only plausible inference from the Master Complaint is that it was **NECC’s conduct**—and not anything UniFirst allegedly did—that proximately caused plaintiffs’ harm. It is well-settled under the law of all relevant jurisdictions that, when “extraordinary” actions of another party—actions that were not “foreseeable”—intervene in a sequence of events, those intervening acts are considered a “superseding cause” that breaks the chain of proximate causation. *Lynch v. Scheininger*, 744 A.2d 113, 123 (N.J. 2000); *see also, e.g., Control Techniques, Inc. v. Johnson*, 762 N.E.2d 104,

¹⁶ Although plaintiffs allege that UniFirst “was hired by NECC to clean the NECC and Ameridose clean rooms,” Compl. ¶ 5, in fact, UniFirst had no contract with Ameridose, and the CCSA makes clear that UniFirst cleaned only at NECC’s Framingham facility—it never cleaned any part of Ameridose’s Westborough facility where the FDA identified these significant deficiencies. *See* Hemani Decl. Ex. B (CCSA).

107 (Ind. 2002).¹⁷ The law of “superseding cause” reflects the universal view that, while a person must “anticipate or foresee what usually will happen” and what “was probable according to the usual experience of persons,” he or she need not “anticipate and provide against what is unusual or unlikely to happen, or that which is remotely possible.” *Ward v. Univ. of the South*, 354 S.W.2d 246, 250 (Tenn. 1962); *see also, e.g., Rains v. Bend of the River*, 124 S.W.3d 580, 593 (Tenn. Ct. App. 2003) (“[N]o person is expected to protect against harms from events that he or she cannot reasonably anticipate or foresee or which are so unlikely to occur that the risk, although recognizable, would commonly be disregarded.”). Thus, where a complaint alleges intervening conduct by a third party that is “wrongful, extraordinary, [or] unusual,” those allegations justify dismissal for want of proximate cause. *Patterson v. Cabala*, 2006 WL 2271319 at *4 (Mich. Ct. App. Aug. 8, 2006).¹⁸

Plaintiffs do not (and could not) plausibly suggest that UniFirst proximately caused their injuries because the Master Complaint unambiguously asserts that NECC’s “wrongful,

¹⁷ *See also* *Louria v. Brummett*, 916 S.W.2d 929, 930 (Tenn. Ct. App. 1995) (“[I]f an injury is not reasonably foreseeable, a third party’s criminal act constitutes a superseding, intervening cause, which will relieve the defendant of liability.”); *Moning v. Alfano*, 254 N.W.2d 759, 765-66 (Mich. 1977) (“intervening causes” that are not foreseeable “supersede the defendant’s responsibility”); *Savage Truck Line v. T aylor*, 69 S.E.2d 478, 482 (Va. 1952) (holding that an intervening cause will “be deemed to have broken the causal connection” if it was not reasonably foreseeable by the wrongdoer); *see also Gilmore v. Shell Oil Co.*, 613 So. 2d 1272, 1275 (Ala. 1993); *Goldberg v. Florida Power & Light Co.*, 899 So. 2d 1105, 1116 (Fla. 2005); *Bentley v. Saunemin Twp.*, 413 N.E.2d 1242, 1245 (Ill. 1980); *Briscoe v. Amazing Products, Inc.*, 23 S.W.3d 228, 229 (Ky. Ct. App. 2000); *Pittway Corp. v. Collins*, 973 A.2d 771, 791-92 (Md. 2009); *Lennon v. Pieper*, 411 N.W.2d 225, 228 (Minn. Ct. App. 1987); *Boynton v. Figueroa*, 913 A.2d 697, 706 (N.H. 2006); *Hairston v. Alexander Tank & Equip. Co.*, 311 S.E.2d 559, 565 (N.C. 1984); *Cascone v. Herb Kay Co.*, 451 N.E.2d 815, 819 (Ohio 1983); *Walsh v. Israel Couture Post*, 542 A.2d 1094, 1097 (R.I. 1988); *Phan Son Van v. Pena*, 990 S.W.2d 751, 754 (Tex. 1999); *Bishop v. S.C.Dep’t of Mental Health*, 502 S.E.2d 78, 82-84 (S.C. 1998).

¹⁸ For example, in *Patterson v. Cabala*, a driver negligently crashed his car, leading the plaintiff, who was a police officer, to come to the scene. A second driver, who was driving under the influence of alcohol, subsequently crashed into the first driver’s car, seriously wounding the plaintiff police officer. The plaintiff sued both drivers, but the Michigan Court of Appeals held as a matter of law that the drunk driver’s conduct was a superseding cause that relieved the first driver of liability. 2006 WL 2271319 at *4 (Mich. Ct. App. Aug. 8, 2006). The court explained that the second accident was “clearly due to the independent actions of a highly culpable third person, [] whose action of driving his vehicle while under the influence of liquor was wrongful, extraordinary, and unusual,” and thus constituted “an independent superseding cause of plaintiff’s injury that was not foreseeable.” *Id.*

extraordinary, and unusual” conduct was a superseding cause of their harm. *Id.* As the Master Complaint alleges, the MDPH and the FDA identified “serious deficiencies and significant violations of pharmacy law and regulations [by NECC] that clearly placed the public’s health and safety at risk.” Compl. ¶ 75. For example:

- The cleanrooms used by NECC to compound products were not appropriately sealed, allowing contaminants to infiltrate the room, Compl. ¶ 83;
- NECC failed on a daily basis to comply with USP 797’s cleaning and sterilization requirements, Compl. ¶ 84;
- NECC failed to properly sterilize its products in the autoclave, Compl. ¶ 79;
- NECC created an environment that made the cleanrooms particularly “susceptible to microbial growth” by, among other things, not running any air-conditioning in the cleanrooms at night and allowing pools of water to collect from a leaky boiler right outside the cleanrooms, Compl. ¶¶ 86, 97; and
- NECC blatantly disregarded the results of its sterility testing, which revealed significant levels of contaminants in its cleanrooms and in its products—choosing nonetheless to continue to manufacture and ship those products to facilities around the country (sometimes without even waiting for the results of its sterility testing), Compl. ¶¶ 94-95.

In short, because the Master Complaint makes abundantly clear that plaintiffs’ injuries were caused by NECC’s unforeseeable “wrongful, extraordinary, and unusual” conduct, *Patterson v. Cabala*, 2006 WL 2271319 at *4—and not by anything that UniFirst did or did not do—plaintiffs’ negligence claim against UniFirst must be dismissed.¹⁹

II. PLAINTIFFS’ CHAPTER 93A CLAIM AGAINST UNIFIRST (COUNT VI) FAILS AS A MATTER OF LAW.

The claim asserted against UniFirst under M.G.L. Chapter 93A fails for three separate reasons. First, choice-of-law analysis precludes plaintiffs from suing UniFirst under Chapter

¹⁹ In addition to the arguments presented here, there are numerous reasons why, under the law of particular states that may be relevant to a subset of cases, plaintiffs’ allegations are insufficient to establish that UniFirst proximately caused their injuries. Because those arguments are not common to all plaintiffs, however, we reserve them for subsequent motions to dismiss the individual cases.

93A. Second, as discussed, the facts pleaded in the Master Complaint do not give rise to a plausible inference that UniFirst's conduct proximately caused plaintiffs' injuries, as required to state a claim under Chapter 93A. And, third, the Master Complaint does not allege any facts that plausibly suggest that UniFirst engaged in "unfair" or "deceptive" conduct.

A. Choice-of-Law Rules Require Dismissal of Plaintiffs' Chapter 93A Claim.

Although every state has adopted some form of consumer protection or consumer fraud statute akin to Chapter 93A, *see* Compl. ¶ 264 (listing statutes), such statutes differ in numerous ways, including their scope, statutes of limitations, and standards for reliance, causation, scienter, and damages.²⁰ And because all choice-of-law rules dictate the applicability of some other states' consumer protection law, a "claim under Chapter 93A is not actionable" and must be dismissed. *Crellin Technologies, Inc. v. Equipmentlease Corp.*, 18 F.3d 1, 12 (1st Cir. 1994).²¹

An MDL court applies the choice-of-law rules of the states in which each transferor court sits. *See, e.g., In re Volkswagen and Audi Warranty Extension Litig.*, 692 F.3d 4, 18-19 (1st Cir. 2012). Virtually all of the cases that include claims against UniFirst were transferred to this MDL proceeding from courts in states that follow one of three choice of law principles: (1) a rule or presumption of *lex loci*, (2) a rule or presumption of *lex fori*, and (3) the "most significant

²⁰ *See, e.g., In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 84 (D. Mass. 2005) (citing disparities among consumer protection statutes in different jurisdictions); *In re Ford Motor Co. Ignition Switch Products Liab. Litig.*, 174 F.R.D. 332, 351 (D.N.J. 1997) (noting "a multitude of different standards and burdens of proof with regard to plaintiffs' ... consumer protection claims"); *Tracker Marine, L.P. v. Ogle*, 108 S.W.3d 349, 352 (Tex. Ct. App. 2003) (describing differences between state consumer protection statutes and concluding that "the scope, procedures, and remedies of those statutes vary considerably"). By way of example, Massachusetts and Indiana require consumers to provide notice before filing suit while Michigan does not; Massachusetts and Indiana allow for punitive damages while Michigan does not; and Massachusetts and Michigan both allow consumer suits without proof of reliance while Indiana does not.

²¹ *See also Reicher v. Berkshire Life Ins. Co. of Am.*, 360 F.3d 1, 4-5 (1st Cir. 2004) (holding that under Massachusetts choice of law rules, Maryland law governed dispute over insurance contract, not Chapter 93A); *Value Partners S.A. v. Bain & Co., Inc.*, 245 F. Supp. 2d 269, 278 (D. Mass. 2003) (dismissing Chapter 93A claim because choice of law pointed towards Brazilian consumer protection statute).

relationship test,” as articulated in the Restatement (Second) of Conflict of Laws.²² Under any of these three choice-of-law standards, plaintiffs must bring suit under the consumer protection law of the states in which they reside, were injured, or initially chose to sue—and not under Massachusetts’s Chapter 93A.

Of the plaintiffs who have brought claims against UniFirst, at least 70 filed their claims in states that apply either a rule or presumption of *lex loci*—meaning that they apply the law of the jurisdiction where the injury occurred.²³ Because it is undisputed that no plaintiff was injured in Massachusetts, these 70-plus plaintiffs are not entitled to sue under Chapter 93A.²⁴

Additionally, more than 130 plaintiffs initially filed their claims in Michigan, where courts apply a presumption of *lex fori*—meaning that they presumptively apply the law of the jurisdiction where plaintiff chose to file suit.²⁵ Thus, the 130-odd plaintiffs who initially filed suit in Michigan also are not entitled to avail themselves of Chapter 93A.²⁶

²² A handful of plaintiffs filed suit in Minnesota, which applies an “interest analysis,” pursuant to which courts consider advancement of the forum’s governmental interests and application of the better rule of law. *See DeRemer v. Pac. Intermountain Exp. Co.*, 353 N.W.2d 694 (Minn. Ct. App. 1984). For the same reasons that Massachusetts’s consumer protection statute would not apply under the Restatement test, *see infra* at 20, Massachusetts’s law also would not apply under the “interest test.”

²³ Maryland, Virginia, and Indiana are *lex loci* states. *See In re Sabin Oral Polio Vaccine Products Liab. Litig.*, 774 F. Supp. 952, 954 (D. Md. 1991); *Jones v. R.S. Jones & Assocs., Inc.*, 431 S.E.2d 33, 34 (Va. 1993); *see also Simon v. United States*, 805 N.E.2d 798, 804-05 (Ind. 2004) (rebuttable presumption of *lex loci*).

²⁴ In states like Indiana with *lex loci* presumptions, where the plaintiff’s domicile and injury are in the same place, as is typically the case here, courts have found no reason to disregard this presumption. *See Alli v. Eli Lilly & Co.*, 854 N.E.2d 372, 379 (Ind. Ct. App. 2006) (holding under Indiana choice-of-law rules that the *lex loci* presumption was not overcome in a products liability case where the decedent “lived and worked in Michigan[,] consulted with a Michigan physician and received all of his medical treatment in Michigan[,] deci[ded] to take Prozac . . . in Michigan[,] . . . took Prozac in Michigan and took his own life there as well.”).

²⁵ *See, e.g., Sutherland v. Kennington Truck Serv., Ltd.*, 562 N.W.2d 466, 471 (Mich. 1997).

²⁶ The presumption of *lex fori* is not overcome where, as here, plaintiffs brought suit in the states where they reside and where they were injured—and where none of the plaintiffs resides or was injured in Massachusetts. *See Sutherland*, 562 N.W.2d at 471-473 (applying Michigan law when accident occurred in Michigan, even though plaintiffs and defendants were residents of other jurisdictions, and accident location was Michigan’s only connection to the injury); *Standard Fire Ins. Co. v. Ford Motor Co.*, 723 F.3d 690, 694 (6th Cir. 2013) (concluding that the Michigan Supreme Court and Court of Appeals consider plaintiff’s residence and site of injury as critical factors in determining whether the *lex fori* presumption is overcome).

Finally, more than 300 plaintiffs suing UniFirst filed their claims in states that apply the Restatement test.²⁷ Under the Restatement, in a negligence case, “the local law of the state where the injury occurred determines the rights and liabilities of the parties, unless, with respect to the particular issue, some other state has a more significant relationship . . . to the occurrence and the parties.” Restatement (Second) of Conflict of Laws § 146 (1971).²⁸ Courts have interpreted the Restatement as imposing “a *strong* presumption [] that the law of the place of injury . . . governs the substantive issues[.]” *Townsend v. Sears, Roebuck & Co.*, 879 N.E.2d 893, 905 (Ill. 2007).²⁹ This is true even when the allegedly wrongful conduct happened elsewhere.³⁰

Nothing about this case overcomes the presumption that the law of the place of injury governs. Plaintiffs almost universally were treated with NECC products in their home states,

²⁷ States following the Restatement rules include Florida, New Jersey, Ohio, Tennessee and Texas. *See Tune v. Phillip Morris Inc.*, 766 So. 2d 350, 353 (Fla. Dist. Ct. App. 2000); *Fu v. Fu*, 733 A.2d 1133, 1138 (N.J. 1999); *Morgan v. Biro Mfg. Co.*, 474 N.E.2d 286 (Ohio 1984); *Hataway v. McKinley*, 830 S.W.2d 53 (Tenn. 1992); *Thomas v. N.A. Chase Manhattan Bank*, 994 F.2d 236, *remanded after appeal*, 1 F.3d 320 (5th Cir. 1993) (Texas). Massachusetts follows a “functional approach,” akin to the Restatement. *See, e.g., Lou v. Otis Elevator Co.*, 933 N.E.2d 140, 150 (Mass. App. Ct. 2010) (“Massachusetts generally follows a functional approach to resolving choice of law questions on substantive matters, eschewing reliance on any particular choice-of-law doctrine. . . . Though we do not tie our analysis to any single doctrine, examination of our cases reveals that we often find useful guidance in the Restatement (Second) of Conflict of Laws.”).

²⁸ Courts applying the Restatement test to statutory claims, such as the Chapter 93A claims here, look to the section of the Restatement that is most similar to the claim alleged—in this case, the section governing negligence claims. *See, e.g.,* Compl. ¶ 286 (“UniFirst’s negligence and gross negligence alleged herein constitutes unfair competition or unfair or deceptive acts or practices or constitute false representations in violation of M.G.L. c. 93A.”); *see also, e.g., Crellin Technologies, Inc. v. Equipmentlease Corp.*, 18 F.3d 1, 11-12 (1st Cir. 1994).

²⁹ *See also Montgomery v. Wyeth*, 580 F.3d 455, 459 (6th Cir. 2009) (noting that Tennessee’s most significant relationship test “provides a default rule whereby trial courts can apply the law of the place where the injury occurred”) (internal quotations omitted); *P.V. ex rel. T.V. v. Camp Jaycee*, 962 A.2d 453, 461 (N.J. 2008) (“Section 146 recognizes the intuitively correct principle that the state in which the injury occurs is likely to have the predominant, if not exclusive, relationship to the parties and issues in the litigation.”); *Spinuzzi v. ITT Sheraton Corp.*, 174 F.3d 842, 844 (7th Cir. 1999) (“[I]n the absence of unusual circumstances, the highest scorer on the ‘most significant relationship’ test is—the place where the tort occurred.”).

³⁰ Indeed, the comments to the Restatement make clear that, when “conduct and injury occur in different states . . . the local law of the state of injury will usually be applied.” Restatement (Second) of Conflict of Laws § 146. cmt. e. And the local law is “most likely to be applied when the injured person has a settled relationship to that state, either because he is domiciled or resides there or because he does business there,” *id.*—which appears to be universally true here.

and, thus, were injured in their home states. And courts uniformly conclude that, under the Restatement, when plaintiffs are injured by pharmaceutical products manufactured in a different state, the law of each plaintiff's home state governs.³¹ This is particularly true for consumer protection claims, given that the purpose of consumer protection laws is to protect consumers.³² As explained by another court in this district: "The conclusion that the home state of the consumer has a more significant relationship to the alleged fraud than the place of business of the defendant is in accordance with the principles of Restatement § 6, since state consumer protection statutes are designed to protect consumers rather than to regulate corporate conduct." *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 83 (D. Mass. 2005) (Saris, J.) (emphasis added).³³

Here, each of the plaintiffs' home states has an interest in protecting consumers from in-state injuries caused by foreign corporations. Accordingly, under any choice-of-law test, this court cannot apply the consumer protection law of Massachusetts—a state in which not a single plaintiff resides, and not a single plaintiff was injured.

³¹ See, e.g., *Montgomery v. Wyeth*, 580 F.3d 455, 460 (6th Cir. 2009) (Tennessee law applies because "Tennessee is where Montgomery sustained her injury, Tennessee is her place of domicile and residence, Tennessee is where she intended to and did use almost all of her Pondimin tablets, and Tennessee is the state where she was diagnosed and treated for her injury."); *Wahl v. Gen. Elec. Co.*, --- F.Supp.2d ----, 2013 WL 6048187, at *7 (M.D. Tenn. Nov. 14, 2013) (noting that in pharmaceutical liability cases "the Sixth Circuit, courts within this circuit, and courts in other circuits . . . have uniformly concluded that the law of the plaintiff's place of injury applies"); *Rowe v. Hoffman-La Roche, Inc.*, 917 A.2d 767, 776 (N.J. 2007) ("To allow a life-long Michigan resident who received an FDA-approved drug in Michigan and alleges injuries sustained in Michigan to by-pass his own state's law and obtain compensation for his injuries in this State's courts completely undercuts Michigan's interests, while overvaluing our true interest in this litigation.").

³² Notably, Chapter 93A is titled "Regulation of Business Practices For Consumers' Protection" (emphasis added). As such, it is intended to address conduct "directly or indirectly affecting the people of this commonwealth," M.G.L. ch. 93A § 1(b).

³³ See also *Tracker Marine, L.P. v. Ogle*, 108 S.W.3d 349, 356 (Tex. App. 2003) ("Consumer protection statutes are intended to protect consumers; one would expect the state where those consumers reside would have the most significant interest."); *In re Ford Motor Co. Ignition Switch Products Liability Litig.*, 174 F.R.D. 332, 348 (D.N.J. 1997) ("Each plaintiff's home state has an interest in protecting its consumers from in-state injuries caused by foreign corporations and in delineating the scope of recovery for its citizens under its own laws.").

B. Plaintiffs’ Chapter 93A Claim Fails Because UniFirst’s Alleged Wrongdoing Did Not Cause Plaintiffs’ Injuries.

Even if plaintiffs could bring claims under Chapter 93A (which they cannot), this Court would be required to dismiss those claims because, for the reasons articulated above, *see supra* Section I.B, plaintiffs have not alleged that UniFirst’s conduct was either a “but for” or a proximate cause of their injuries. *See, e.g., McCann v. Davis, Malm & D’Agostine*, 669 N.E.2d 1077, 1079 (Mass. 1996) (holding that proof of proximate cause is required to prevail under a Chapter 93A claim).

C. The Master Complaint Does Not Allege Facts Sufficient to Establish that UniFirst Engaged in “Unfair” or “Deceptive” Conduct.

Finally, plaintiffs’ Chapter 93A claim against UniFirst fails because the Master Complaint does not, and could not, allege that UniFirst engaged in any “unfair or deceptive acts or practices,” as required to state a claim under Chapter 93A. Mass. Gen. Laws ch. 93A, § 2 (2004).

The allegations against UniFirst in the Master Complaint do not give rise to any plausible inference that UniFirst behaved unfairly. For purposes of Chapter 93A, “[a]n action is ‘unfair’ if it is ‘(1) within the penumbra of a common law, statutory, or other established concept of unfairness; [or] (2) immoral, unethical, oppressive, or unscrupulous.’” *Gossels v. Fleet Nat’l Bank*, 902 N.E.2d 370, 378 (Mass. 2009) (citations omitted). “The ‘crucial factors’ in an unfairness inquiry are ‘the nature of [the] challenged conduct and [] the purpose and effect of that conduct.’” *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 184-85 (1st Cir. 2009) (quoting *Mass. Employers Ins. Exch. v. Propac–Mass, Inc.*, 648 N.E.2d 435, 438 (Mass. 1995) (citing *PMP Assocs., Inc.*, 321 N.E.2d 915 (Mass. 1975))).

The Master Complaint alleges that certain UniFirst employees failed to comply with best practices in carrying out their duties at NECC. But it does not allege that such conduct was

intentional or that anyone at UniFirst acted unethically or with the purpose of harming consumers. Nor does it allege that the conduct of UniFirst's employees violated any statute or regulation with which UniFirst was obligated to comply. Indeed, plaintiffs do not even allege that UniFirst violated any of its contractual obligations under the CCSA. At most, the allegations against UniFirst in the Master Complaint describe merely negligent conduct that cannot give rise to liability under Chapter 93A.³⁴

The Master Complaint likewise fails to allege that UniFirst engaged in any "deceptive" conduct. For purposes of Chapter 93A, "an act or practice is deceptive 'if it could reasonably be found to have caused a person to act differently from the way he or she otherwise would have acted.'" *Incase Inc. v. Timex Corp.*, 488 F.3d 46, 57 (1st Cir. 2007) (citation omitted). Here, the Master Complaint does not, and could not, allege that UniFirst made any representations of any kind to the plaintiffs, much less any representations that could be deemed "deceptive."³⁵

In short, because there is nothing "unfair" or "deceptive" about the conduct that the Master Complaint attributes to UniFirst, plaintiffs' Chapter 93A claims cannot be sustained.

III. PLAINTIFFS' CLAIMS FOR WRONGFUL DEATH (COUNT XII), LOSS OF CONSORTIUM (COUNT XIII), AND PUNITIVE DAMAGES (COUNT XIV) FAIL AS A MATTER OF LAW.

Because plaintiffs have failed to state a primary claim against UniFirst, their subsidiary claims for wrongful death,³⁶ loss of consortium,³⁷ and punitive damages³⁸ likewise fail.

³⁴ "[A]n unfair or deceptive act requires more than a finding of negligence," *Darviris v. Petros*, 812 N.E.2d 1188, 1192 (Mass. 2004) (citing *Meyer v. Wagner*, 709 N.E.2d 784 (Mass. 1999), *Poly v. Moylan*, 667 N.E.2d 250 (Mass. 1996) and *Squeri v. McCarrick*, 588 N.E.2d 22 (Mass. App. 1992)). "There must in addition be evidence that the negligence was or resulted in an unfair or deceptive act or practice." *Id.*

³⁵ Although the Master Complaint cites to certain UniFirst marketing materials, *see* Compl. ¶¶ 139-140, it does not allege that either the plaintiffs or NECC ever saw, read, reviewed, or relied upon the statements contained in such materials, nor does it allege that the statements were in any way untrue.

³⁶ *See, e.g., Wesche v. Mecosta Cnty. Rd. Comm'n*, 746 N.W.2d 847, 856 (Mich. 2008) ("[T]he wrongful-death act is essentially a 'filter' through which the underlying claim may proceed."); *Harris v. Birmingham Hide & Tallow Co., Inc.*, 589 So.2d 150, 151 (Ala. 1991); *Jenkins v. W.L. Roberts, Inc.*, 851 So. 2d 781, 783 (Fla. Dist. Ct. App. 2003); *Carter v. SSC Odin Operating Co., LLC*, 976 N.E.2d 344, 358 (Ill. 2012); *Tom v. Volda*, 654

Additionally, plaintiffs' claim against UniFirst for punitive damages fails as a matter of law because (1) in several relevant jurisdictions, punitive damages are not recoverable at all,³⁹ and (2) those jurisdictions that do provide for punitive damages limit their recovery to circumstances in which a party acted with "a 'quasi-criminal' state of mind" or engaged in

N.E.2d 776, 787 (Ind. Ct. App. 1995); *Richardson v. Rose Trans., Inc.*, 2014 WL 121690, at *11 (E.D. Ky. Jan. 13, 2014); *Grinage v. Mylan Pharm., Inc.*, 840 F. Supp. 2d 862, 872 (D. Md. 2011); *Dumka v. Quaderer*, 390 N.W.2d 200 (Mich. Ct. App. 1986); *Beck v. Groe*, 70 N.W.2d 886, 892 (Minn. 1955); *Cheever v. S. New Hampshire Reg'l Med. Ctr.*, 688 A.2d 565, 567 (N.H. 1997); *Aronberg v. Tolbert*, 25 A.3d 1121, 1130 (N.J. 2011) (citing N.J. Stat. Ann. § 2A:31-1); *Mann v. Henderson*, 134 S.E.2d 626, 629 (N.C. 1964); *Thompson v. Wing*, 637 N.E.2d 917, 923-24 (Ohio 1994); *Almonte v. Kurl*, 46 A.3d 1, 17-18 (R.I. 2012); *Estate of Stokes ex rel. Spell v. Pee Dee Family Physicians, L.L.P.*, 699 S.E.2d 143, 145 (S.C. 2010); *Hames v. State*, 808 S.W.2d 41, 45 (Tenn. 1991); *Russell v. Ingersoll-Rand Co.*, 841 S.W.2d 343, 347 (Tex. 1992); *Baker v. Poolservice Co.*, 636 S.E.2d 360, 365-66 (Va. 2006).

³⁷ See, e.g., *Gross v. City of Dearborn Heights*, 2014 WL 346017 (E.D. Mich. Jan. 30, 2014) ("Even though loss of consortium is an independent claim, it is contingent on a spouse's recovery for injuries sustained.") (internal citations omitted); *Ex parte N.P.*, 676 So. 2d 928, 930 (Ala. 1996); *Gates v. Foley*, 247 So. 2d 40, 45 (Fla. 1971); *Smith v. Gleason*, 504 N.E.2d 240, 242 (Ill. App. 1987); *Durham ex rel. Estate of Wade v. U-Haul Int'l*, 745 N.E.2d 755, 764 (Ind. 2001); *Sergeant v. ICG Knott Cnty., LLC*, 2013 WL 6451210, at *4 (E.D. Ky. Dec. 9, 2013); *Oaks v. Connors*, 660 A.2d 423, 430 (Md. 1995); *Eide v. Kelsey-Hayes Co.*, 427 N.W.2d 488, 489 (Mich. 1988); *Thill v. Modern Erecting Co.*, 170 N.W.2d 865, 869 (Minn. 1969); *Guilfooy v. United Servs. Auto. Ass'n*, 898 A.2d 502, 504 (N.H. 2006); *Neely v. Kossove*, 487 A.2d 788, 790 (N.J. Super. Ct. Law Div. 1984); *Nicholson v. Hugh Chatham Mem'l Hosp., Inc.*, 266 S.E.2d 818, 823 (N.C. 1980); *Bowen v. Kil-Kare, Inc.*, 585 N.E.2d 384, 392 (Ohio 1992); *Sama v. Cardi Corp.*, 569 A.2d 432, 433 (R.I. 1990); *Creighton v. Coligny Plaza Ltd. P'ship*, 512 S.E.2d 510, 523 (S.C. Ct. App. 1998); *Jackson v. Miller*, 776 S.W.2d 115, 117 (Tenn. Ct. App. 1989); *Whittlesey v. Miller*, 572 S.W.2d 665, 667 (Tex. 1978). Furthermore, Virginia does not recognize a claim for loss of consortium. See, e.g., *Carey v. Foster*, 345 F.2d 772, 776 (4th Cir. 1965).

³⁸ See, e.g., Fla. Stat. §§ 768.72(2)–(3) (1986); S.C. Code Ann. § 15-32-520(C) (2011); see also, e.g., *Cheatham v. Pohle*, 789 N.E.2d 467, 473-74 (Ind. 2003) (holding that a claim for punitive damages can only be sustained if it accompanies a viable claim for compensatory damages); *Fonseca v. Golden Living Ctr.-Mountainview*, 2010 WL 3155984 at *10 (E.D. Tenn. Aug. 10, 2010); *Life Ins. Co. of Georgia v. Smith*, 719 So. 2d 797, 806 (Ala. 1998); *Kemner v. Monsanto Co.*, 576 N.E.2d 1146, 1153 (Ill. App. 1991); *Ammon v. Welty*, 113 S.W.3d 185, 188 (Ky. Ct. App. 2002); *VF Corp. v. Wrexham Aviation Corp.*, 715 A.2d 188, 192 n.2 (Md. 1998); *Johns v. Harborage I, Ltd.*, 585 N.W.2d 853, 863 (Minn. Ct. App. 1998); *Kennett v. Delta Air Lines, Inc.*, 560 F.2d 456, 458 (1st Cir. 1977) (applying New Hampshire law); *Smith v. Whitaker*, 734 A.2d 243, 250 (N.J. 1999); *Pittmann v. Hyatt Coin & Gun, Inc.*, 735 S.E.2d 856, 859 (N.C. Ct. App. 2012); *Niskanen v. Giant Eagle, Inc.*, 912 N.E.2d 595, 599 (Ohio 2009); *Palmisano v. Toth*, 624 A.2d 314, 318 (R.I. 1993); *Concrete Spaces, Inc. v. Sender*, 2 S.W.3d 901, 903, 909-911 (Tenn. 1999); *Travelers Indem. Co. of Illinois v. Fuller*, 892 S.W.2d 848, 851-852 (Tex. 1995); *Syed v. ZH Technologies, Inc.*, 694 S.E.2d 625, 634 (Va. 2010).

³⁹ See, e.g., *Gilbert v. DaimlerChrysler Corp.*, 685 N.W.2d 391, 400 (Mich. 2004) ("[C]ourts must be mindful of the fact that punitive damages are available in Michigan only when expressly authorized by the Legislature."). Cf. *Vincent v. Alden-Park Strathmoor, Inc.*, 948 N.E.2d 610, 612 (Ill. 2011) ("Under section 2-604.1 of the Code of Civil Procedure (735 ILCS 5/2-604.1 (West 2006)), plaintiffs asserting causes of action for bodily injury or physical damage to property based on negligence, or on products liability based on any theory or doctrine, are not permitted to include in their complaints a prayer for relief seeking punitive damages.").

“willful and wanton misconduct,” *Cheatham v. Pohle*, 789 N.E.2d 467, 471 (Ind. 2003)⁴⁰—the type of misconduct plainly alleged against NECC **but not alleged against UniFirst.**

CONCLUSION

For the foregoing reasons, the Court should dismiss the Master Complaint as against UniFirst in its entirety and with prejudice.

⁴⁰ See also Ala. Code § 6-11-20 (1987); Fla. Stat. § 768.72(2) (1986); N.J. Stat. Ann. § 2A:15-5.12(a) (1995); N.C. Gen. Stat. Ann. § 1D-15 (1995); S.C. Code Ann. § 15-32-520(D) (2011); Tex. Civ. Prac. & Rem. Code § 41.003 (2003); *Banks v. Mario Indus. of Virginia, Inc.*, 650 S.E.2d 687, 699 (Va. 2007) (“[Punitive] damages may be recovered only where there is misconduct or actual malice, or such recklessness or negligence as to evince a conscious disregard of the rights of others... actual malice [is] a sinister or corrupt motive such as hatred, personal spite, ill will, or a desire to injure the plaintiff.”) (internal quotation marks omitted); *Smith v. Whitaker*, 734 A.2d 243, 254 (N.J. 1999) (“There must be an intentional wrongdoing in the sense of an ‘evil-minded act’ or an act accompanied by a wanton and wilful disregard of the rights of another.”); *Flax v. DaimlerChrysler Corp.*, 272 S.W.3d 521, 531 (Tenn. 2008) (“A verdict imposing punitive damages must be supported by clear and convincing evidence that the defendant acted intentionally, fraudulently, maliciously, or recklessly.”); *Gibson v. Fuel Transp., Inc.*, 410 S.W.3d 56, 59 (Ky. 2013), *reh’g denied* (Oct. 16, 2013); *Darcars Motors of Silver Spring, Inc. v. Borzym*, 841 A.2d 828, 838 (Md. 2004); *Mrozka v. Archdiocese of St. Paul & Minneapolis*, 482 N.W.2d 806, 812 (Minn. Ct. App. 1992); *In re Guardianship of Dorson*, 934 A.2d 545, 549 (N.H. 2007); *Calmes v. Goodyear Tire & Rubber Co.*, 575 N.E.2d 416, 419 (Ohio 1991); *Fenwick v. Oberman*, 847 A.2d 852, 854 (R.I. 2004).

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, James C. Rehnquist, hereby certify that the foregoing document, filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on April 1, 2014.

/s/ James C. Rehnquist